

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

<b>IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</b>	<b>MDL No. 2875</b>  <b>HON. RENEE M. BUMB CIVIL NO. 19-2875 (RMB)</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO  
CLARIFY WHETHER DR. NAGAICH MAY TESTIFY AS TO CERTAIN TOPICS WITH  
RESPECT TO WHICH PLAINTIFFS' EXPERT, MR. RUSS, HAS BEEN PERMITTED  
TO TESTIFY**

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## **INTRODUCTION**

Torrent's request for another bite at the *Daubert* apple, three weeks before trial, should be denied. As Torrent is well aware: expert testimony is *not* admissible where their opinions are not supported by a reliable methodology. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 593–94 (1993). There is no override button that permits introducing unreliable testimony simply because the other party's expert testifies on the same topic only with a reliable methodology.<sup>1</sup> Still, that is exactly what Torrent tries to do here by taking the Court's recent ruling on ZHP expert Ali Afnan entirely out of context.

On September 18, 2024, the Court ruled that where the facts are disputed and two experts have parallel qualifications, "I can't have a plaintiff's expert opining as to a matter that the defendant's expert is not permitted to opine as to" Sept. 18, 2024 Hr'g Tr. 102:14–103:2. Now, Torrent claims that *its* expert, Akhilesh Nagaich should be permitted to testify on the same topics as Plaintiffs' expert, Philip Russ even though he was found to lack a reliable methodology. [ECF 28661 at 9–10.] Though Torrent argues the "logic" of the Court's ruling on Dr. Afnan should apply here, *id.*, this is a false equivalence. The question is not whether two similarly qualified experts can opine as to the same subject matter, but whether an expert who who does not have a reliable methodology can opine on a topic just because another party has an expert testifying on the same topic. The answer, of course, is no.

**First**, Torrent's Motion for an Order "amending or correcting the Court's ruling on the Parties' liability experts" [ECF 2866] filed on September 27, 2024 should be denied as untimely

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<sup>1</sup> Torrent's reliance on *United States v. Lankford*, 955 F.2d 1545, 1552 (11th Cir. 1992), is misplaced. *Lankford* is an out-of-circuit decision that predates the Supreme Court's creation of the *Daubert* framework for evaluating the admissibility of expert testimony. The Court should disregard this outdated, nonbinding decision.

because it was filed more than *nine months* after entry of the Court's order on liability experts in violation of D.N.J. Local Rule 7.1(i), which requires motions for reconsideration to be filed within fourteen days of the order sought to be amended.

**Second**, Torrent concedes, Dr. Afnan's opinions concern different subjects than Dr. Nagaich's. [ECF 2581 at 14–15.] The Court cannot cut and paste its ruling on Dr. Afnan here.

**Finally**, the Court's September 18th decision involving Dr. Afnan was concerned with his and Plaintiffs' experts' qualifications to opine as to adulteration; the reliability of each expert's underlying methodology was not determinative. *See, e.g.*, Sept. 18, 2024 Hr'g Tr. 102:14–103:2. By contrast, the Court's decision to preclude portions of Dr. Nagaich's opinion centered on the Court's conclusion that Dr. Nagaich lacked a reliable methodology both as it related to his assessment of auditor Jenny Yang *and* Torrent's compliance with applicable standards. [ECF 2581 at 14–15.] The Court's ruling on Dr. Afnan—which did not involve reliability determinations—does not translate to Dr. Nagaich's opinions because it simply does not deal with the issue of reliability that runs through the Court's prior decision on Dr. Nagaich's opinions.

The Court should reject Torrent's absurd argument that expert opinions tossed out on *Daubert* due to a lack of reliable methodology can be revived and placed before a jury simply because the other party *does* have a qualified expert using a reliable methodology to testify on the same subjects. That is simply not the law, and it is *not* what the Court said last month when ruling on Dr. Afnan's opinions.

### **BACKGROUND**

In January, the Court granted in part and denied in part Plaintiffs' motion to exclude the testimony of Defendants' expert Akhilesh Nagaich. First, The Court excluded Dr. Nagaich's opinions concerning the qualifications of Torrent's third-party auditor, Jenny Yang, and the audit

performed by Ms. Yang “because Nagaich provides no independent, reliable methodology or reliable metrics.” [ECF 2581 at 14. (citing Nagaich Rep. ¶¶ 73–78)] That is, Dr. Nagaich did not “support[] his opinion that Ms. Jenny Yang was a qualified auditor... He merely *asserts* she was qualified.” [*Id.* (emphasis added)] Second, the Court precluded Dr. Nagaich’s opinions concerning Torrent’s adherence to industry standards and cGMP because Dr. Nagaich avers the basic grounding of his opinion is that Torrent followed industry standards,” and his opinions were “grounded in an assertion that Torrent followed the industry standard and that such standard sufficed to relieve Torrent of liability.” [ECF 2581 at 15] The Court, additionally, stated that “there is no stated methodology in Nagaich’s report” such that it is “completely unclear whether the reviewed documents were cherry picked to highlight Torrent’s compliance.” [ECF 2581 at 14.]

At the same time, the Court denied Defendants’ motion to exclude the testimony of Plaintiffs’ expert Philip Russ. The Court did not preclude Mr. Russ’s report “because he has applied a reliable methodology.” [ECF 2581 at 26.] This methodology included a thorough review of Defendants’ own documents in the context of over 30 years of industry experience. [*Id.*] As described by the Court, Dr. Nagaich did not have a similar level of experience. [ECF 2581 at 14.]

On January 17, 2024, less than two weeks after the Court entered its Order, Defendant ZHP filed a Motion requesting amendment of the Court’s order as to its expert, Ali Afnan. [*See generally* ECF 2591.] Nine months later—three weeks before the case was set for trial, Torrent filed its own Motion requesting amendment of the Court’s order as to Dr. Nagaich. [*See generally* ECF 2866.]

## **ARGUMENT**

### **I. Torrent’s Motion is Untimely**

Though labeled “Motion to Clarify,” Torrent’s Motion is, in effect, a Motion for Reconsideration pursuant to D.N.J. Local Rules 7.1(i). Indeed, the standard on which Torrent relies

in its Memorandum is the standard for a Motion for Reconsideration. [*See* 2866-1 at 11 (citing *Sheehan v. Del. & Hudson Ry. Co.*, 439 F. App'x 130, 133 (3d Cir. 2011).] However, “a motion for reconsideration shall be served and filed within 14 days after the entry of the order...on the original motion.” D.N.J. Local Rule 7.1(i). Judge Kugler’s Order precluding testimony by Dr. Nagaich was issued on January 5, 2024. [ECF 2581.] However, Torrent did not file its Motion effectively seeking reconsideration until September 27, 2024—more than nine months *after* the deadline. [ECF 2866.] Torrent’s Motion is therefore untimely and must be denied for that reason alone.

## **II. The Court’s September 18, 2024 Ruling is Inapplicable to Dr. Nagaich’s Opinions**

Torrent argues that the Court’s September 18 ruling on Dr. Afnan should apply with equal force to Dr. Nagaich. [ECF 2581 at 14–15.] But this argument disregards the key differences between the original *Daubert* rulings on Dr. Afnan and Dr. Nagaich. [*See generally* ECF 2581.] Both the underlying subject matter and the reasons for exclusion differed for each expert’s opinions. The Court’s ruling on Dr. Afnan does not address the issues with Dr. Nagaich’s opinions: whether Dr. Nagaich had a reliable methodology to opine as to auditor qualifications and the legal implications of industry standards.

### **1. Dr. Afnan’s Opinions Involved Different Subject Matter Than Dr. Nagaich’s**

Torrent concedes that the issues on which Dr. Nagaich was precluded from testifying “are *different* from those that applied to Dr. Afnan.” [ECF 2866-1 at 9 (emphasis added).] Specifically, while Dr. Afnan opined as to adulteration, Dr. Nagaich opined as to the qualifications of Torrent’s third-party auditor and the adequacy of her audit as well as Torrent’s compliance with industry standards. [*Id.*] Thus, while the Court has already determined that the subject matter of Dr. Afnan’s previously-excluded opinions is an appropriate subject for expert testimony, the Court has not had

the opportunity—with only weeks remaining before trial—to examine the specific content of Dr. Nagaich’s opinions.

**2. Unlike Dr. Afnan, Dr. Nagaich’s Opinions Were Precluded Because They Lacked a Reliable Methodology**

While Dr. Afnan’s opinions on adulteration were excluded for qualifications reasons, Dr. Nagaich’s opinions on third-party audits, industry standards, and cGMP were excluded *both* because Dr. Nagaich lacked qualification *and* because Dr. Nagaich lacked a reliable methodology. [ECF 2581 at 6–7, 14–15.] The Court’s September 18 ruling modifying that Order as to Dr. Afnan, which only addressed the issue of qualifications, had *no bearing* on any prior reliability determinations. [*Compare* Sept. 18, 2024 Hr’g Tr. with ECF 2581 at 6–7.] The Court’s September 18th ruling is limited to a situation in which two similarly qualified experts *both* testify on one limited subject: what it means to be adulterated. Sept. 18, 2024 Hr’g Tr. at 57:4–8, 102:14–18. It does not address the present situation: when the Court’s finding that the expert did not utilize a reliable methodology is the basis of the entire decision. [*See* ECF 2581 at 14–15.]

Torrent claims that because both Dr. Nagaich and Plaintiffs’ expert, Mr. Russ reviewed documents, Dr. Nagaich should be deemed to use the same reliable method as Mr. Russ. [ECF 2866-1 at 11.] This superficial similarity is no substitute for the careful analysis of both expert’s reports and testimony *already* performed by the Court when it engaged in it performed its *Daubert* gatekeeping function. As the Court explained, in fact, Dr. Nagaich and Mr. Russ did *not* have the same methodology. First, while Mr. Russ reviewed all pertinent documents and did so against the backdrop of thirty years’ experience advising pharmaceutical management on cGMP, Dr. Nagaich lacked this experience and, further *did not review all pertinent documentation*. [ECF 2851 at 13–15, 25–27.] Thus, while the Court was confident in Mr. Russ’s complete analysis of the record, it could not rule out cherry-picking by Dr. Nagaich to suggest that Torrent had complied with cGMP.

[*Id.*] In effect, Dr. Nagaich’s “methodology” was unreliable because he did not review all documents and obtain an accurate picture of Torrent’s practices before coming to his conclusions. [*Id.*] *See also Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F.Supp. 449, 461–62 (E.D. Pa. 2014) (“cherry picking is always a concern.”).

Similarly, with respect to Torrent’s third-party auditor Jenny Yang, Dr. Nagaich reviewed documents but was unable to *explain* his conclusions.<sup>2</sup> Dr. Nagaich simply “read and reviewed” documents before opining with “no independent, reliable methodology or reliable metrics” to support his conclusion,” *compare* [ECF 2581 at 14 with Nagaich Rep. at ¶¶ 73–78, ECF 2301-3.] Dr. Nagaich stated that Ms. Yang was qualified—but he never said why and he never explained *how* he reached that conclusion. [*Id.*] It is for good reason that the Court excluded Dr. Nagaich’s unsupported assertions that Torrent auditor Yang was unqualified. The Third Circuit has long held that “‘subjective belief or unsupported speculation’” is not reliable, *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 590 (1993)). Without tracing his claims that Ms. Yang was qualified or her audits were performed adequately to any real metrics or analysis, there is no reason to believe that they *were*. Torrent’s attempt to relitigate *Daubert* fails because, still, they are left with an expert who is reliant on bald assertions of work performed with no explanation of what was actually done.

Regardless, the Court cannot simply apply its ruling involving Dr. Afnan to Dr. Nagaich. What Torrent is asking the Court to do is relitigate *Daubert* three weeks before trial, and that task would require the Court to parse the expert reports and depositions, take testimony, and hear further arguments on the briefs—tasks the Court already completed in 2023.

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<sup>2</sup> Torrent’s representation in its Memorandum that Mr. Russ reviewed only a single document is simply false.



**CONCLUSION**

For the foregoing reasons, Plaintiffs respectfully request that Torrent's Motion be denied in its entirety.

Dated: October 8, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 8, 2024, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ Daniel Nigh

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